

## AWAKE PRONE Newsletter

### COVID-19 Clinical Trials

## Dear Investigators and Study Coordinators,

The **AWAKE PRONE** trials, **COVI- PRONE** and **CORONA** have had great success since the last AWAKE PRONE Newsletter update.

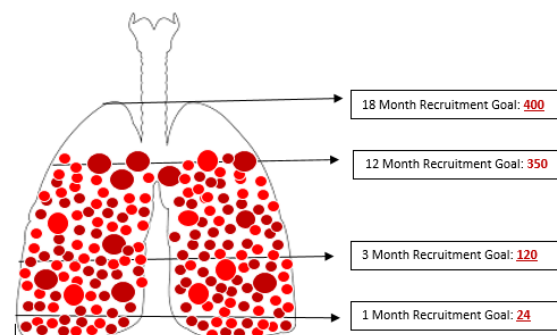
The **COVI-PRONE** has increased the trial sample size and continues to recruit across the 20 active sites, working towards completing enrollment for the **COVI-PRONE** trial.

The **CORONA** trial has reached a total of 13 patients enrolled, and is focused on continuing to on board new sites to increase recruitment.

## Recruitment Report: COVI-PRONE

<u>Site Name:</u>	<u>Site Number:</u>	<u>Total Number Enrollment:</u>
Riyadh, King Abdulaziz Medical City	176	60
Jeddah, King Abdulaziz Medical City	177	12
King Fahd Hospital of the University	178	37
Riyadh, King Faisal Specialist Hospital and Research Centre	179	36
NGHA , King Abdulaziz Hospital	211	11
Madinah, Prince Mohammed bin Abdulaziz Hospital	185	2
St. Joseph's Healthcare Hamilton	001	31
Juravinski Hospital	398	9
Hamilton General Hospital	399	1
Niagara Heath Science -St. Catharines	400	7
South Health Campus (SHC)	401	11
Foothills Medical Centre (FMC)	402	28
Rockyview General Hospital (RGH)	403	10
Peter Lougheed Centre (PLC)	404	43
Mount Sinai Hospital	405	11
Jaber AL Ahmed hospital ( JAH )	9	22
CHU de Québec – Université Laval	10	5
University Health Network (TGH)	11	1
Al-Amiri Hospital	12	24
University of Texas Health Science	13	23

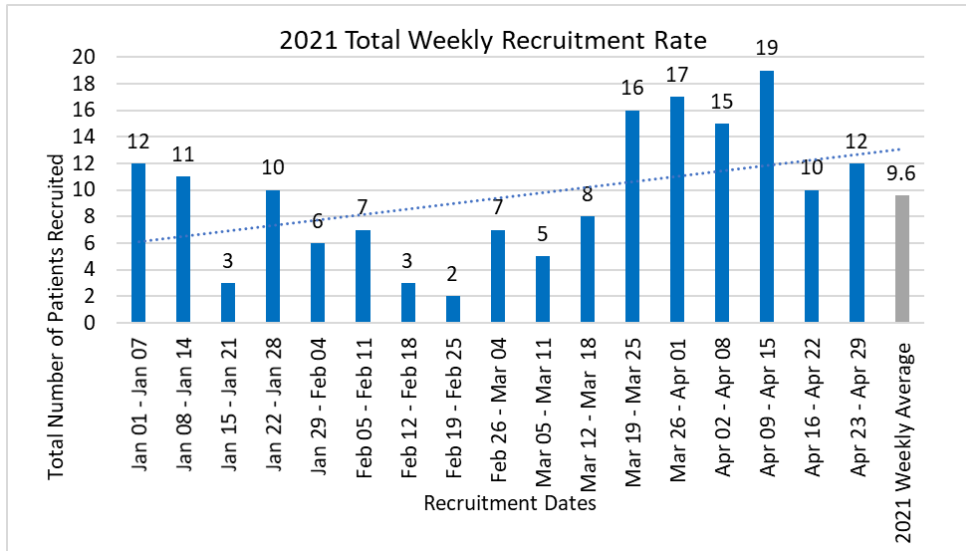
<u>Method Center:</u>	<u>Total Number Enrollment:</u>
North American Recruitment	180
Saudi Arabian Recruitment	158
Kuwait Recruitment	46
<b>Total COVI-PRONE Enrollment:</b>	<b>384</b>



**We have reached 96.0% of our adjusted total recruitment goal!**



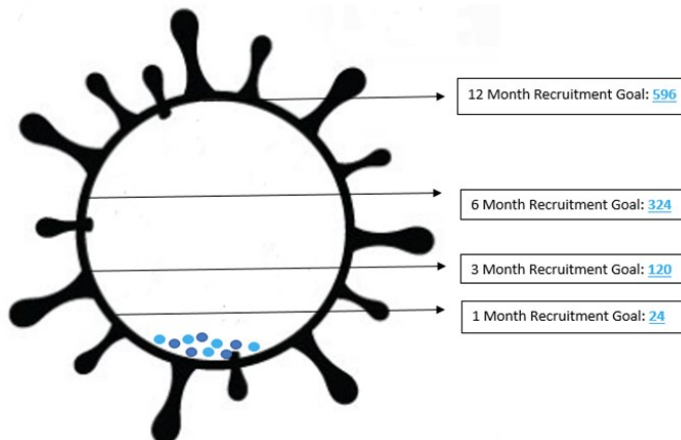
## 2021 Weekly Recruitment: COVI-PRONE



## Recruitment Report: CORONA

Site Name:	Site Number:	Total Number Enrollment:
Peter Lougheed Centre (PLC)	01	6
Rockyview General Hospital (RGH)	02	0
South Health Campus (SHC)	03	0
Foothills Medical Centre (FMC)	04	2
St. Joseph's Healthcare Hamilton	05	5
Niagara Health Science	06	0
CHU de Québec – Université Laval	07	0

**Total CORONA Enrollment:** 13



**AWAKE PRONE POSITION IN HYPOXEMIC PATIENTS WITH CORONAVIRUS DISEASE 19**  
**COVI-PRONE**  
A Randomized Clinical Trial

SUSPECTED or CONFIRMED COVID-19 Patients | Hypoxic RESPIRATORY failure |  $\geq 0.4 \text{ FiO}_2$

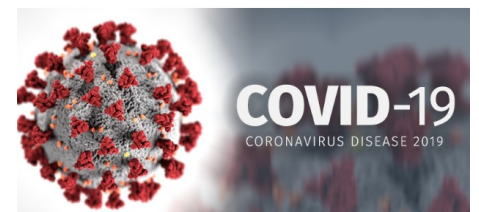
**RANDOMIZATION**

PRONING | NO PRONING

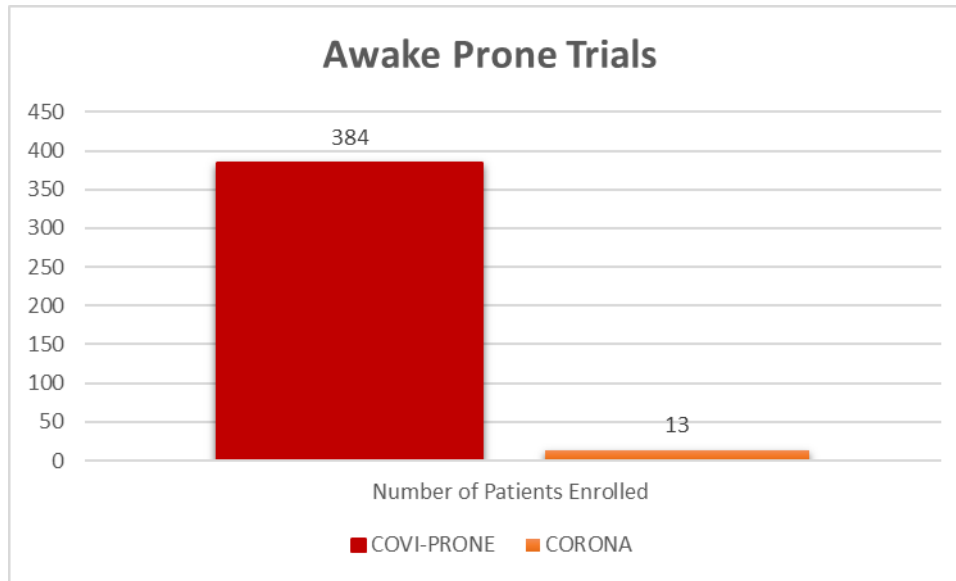
Endotracheal intubation within 36 days (primary outcome)

**SECONDARY OUTCOMES**

- MORTALITY
- INVASIVE MECHANICAL VENTILATION FREE DAYS
- NON-INVASIVE VENTILATION FREE DAYS
- ICU LENGTH OF STAY
- HOSPITAL LENGTH OF STAY
- SpO2: FIO2 RATIO AT 1 HOUR, 4 HOUR AND 8 HOURS
- COMPLICATIONS



## AWAKE Prone Recruitment



### Recruitment Barriers:

Some sites have experienced the following barriers to recruitment:

#### Clinical Equipoise and Buy-in

**ISSUE:** Physicians/care team members express strong belief of benefit or detriment to awake prone practice

**SOLUTION:** Continue to education and provide information highlighting existing equipoise and the importance of the trials.

#### Care Team Engagement

**ISSUE:** Care team engagement/education on protocol conduct.

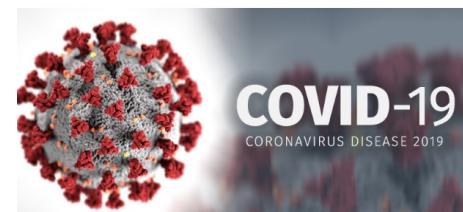
**SOLUTION:** Ongoing trial conduct education. Open line of communication and access to the research team to provide guidance.

#### Access to Patient Population

**ISSUE:** Access to the patient population for enrolment.

**SOLUTION:** This is a hard barrier to overcome, however continued education of care team to identify eligible patients and ongoing screening will facilitate access to those patients who are eligible and increase the chance of enrollment.

\*Please contact any member of the Method Center team for more support.



## Confirmed & Suspected COVID-19 Cases:

Active screening for the Awake Prone Trials is extremely important to ensure optimal enrollment.

For both the **COVI-PRONE** and **CORONA** trial, a patient with either a **Confirmed** or **Suspected** COVID-19 diagnosis can be enrolled in either trial. **Suspected cases are curial as flu season starts.** We anticipate the number of eligible patients will increase.

A **Suspected** COVID-19 case can be considered even if the patient has received a negative swab, but the care team still suspects a COVID-19 diagnosis. (For example: a second swab or sputum sample has been ordered, or there is still a clinical suspicion of COVID-19.)

Please be mindful to continue to screen both **Confirmed** and **Suspected** COVID-19 cases .

## CORONA: Site Participation

Help us meet our recruitment goals for the **CORONA** trial.

Contact the **Method Center** if your **COVI-PRONE** site has eligible patients who cannot be enrolled due to **DNI/DNR** status, and you think you could also contribute to **CORONA** enrolment.

Or perhaps you know of another site who may be interested?

## Newsletter Updates:

The **AWAKE PRONE** Newsletter will be sent out on a regular basis to update all of the involved members of the trials on study enrollment, progression of the study, as well as helpful information collected by the Method Centers from the members conducting the **Awake Prone** Trials at each clinical site. Please send any tips, concerns, or suggestions to publish in **Awake Prone** trial Newsletter to:

The **Awake Prone** Trial group methods center:  
**Kate Nelson: [nelsonk@stjosham.on.ca](mailto:nelsonk@stjosham.on.ca)**

